

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ROCHE DIAGNOSTICS CORPORATION,

Plaintiff,

v.

MESO SCALE DIAGNOSTICS, LLC,

Defendant.

C.A. No. 17-189-LPS

MESO SCALE DIAGNOSTICS, LLC,

Counterclaim Plaintiff,

v.

ROCHE DIAGNOSTICS CORPORATION, and
BIOVERIS CORPORATION,

Counterclaim Defendants.

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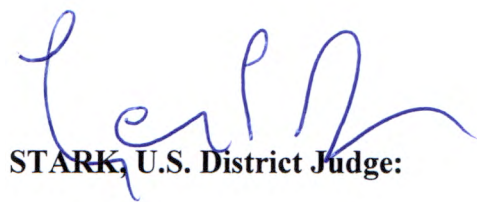
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MEMORANDUM OPINION

March 21, 2019
Wilmington, Delaware

UNSEALED ON
MARCH 25, 2019



STARK, U.S. District Judge:

Plaintiff Roche Diagnostics Corporation brought this declaratory judgment suit against Defendant Meso Scale Diagnostics, LLC (“Meso”) seeking judgment that it does not infringe Meso’s license rights to patented diagnostics detection technology known as electrochemiluminescence (“ECL”). (See D.I. 1) Meso filed counterclaims against Roche Diagnostics Corporation and BioVeris Corporation (“BioVeris” and, collectively, “Roche”) asserting infringement of ten patents. (See D.I. 42-1)

Presently before the Court is Roche’s Motion for Summary Judgment (D.I. 98) regarding the scope of Meso’s license to practice the asserted patents.¹ Having considered the parties’ briefs and numerous exhibits (see D.I. 99-101, 109-10, 116-17) and having heard oral argument on October 23, 2018 (see D.I. 124 (“Tr.”)), the Court will deny the motion.

BACKGROUND

The following facts are not disputed. In 1992, IGEN and Boehringer Mannheim GmbH (“BM”) executed a license agreement (“1992 License”) wherein IGEN authorized BM to develop diagnostic instruments with ECL detection. (D.I. 99 at 3; Ex. 4²) In 1998, Roche purchased

¹The Scheduling Order divided discovery into two tracks. (See D.I. 25 at 5-8) Track 1 relates to “the scope of Meso Scale’s exclusive license rights under the 1995 IGEN/MSD License Agreement (as amended)” and “functional and technological aspects of the accused products, including but not limited to how those products work and can be used by customers.” (*Id.* at 5) The pending motion was authorized as a Track 1 dispositive motion that might “dispose of all or part of the case based solely upon the definition and/or scope of Meso Scale’s license rights.” (*Id.* at 7)

²Exhibits 1-26, Exhibits 27-58, and Exhibits 59-63 refer to the Exhibits filed by Roche in D.I. 100, 101, and 117, respectively. Exhibits A-FF refer to the Exhibits filed by Meso in D.I. 110.

BM, so Roche became the licensee under the 1992 License. (*See* D.I. 109 at 6 n.1; Ex. O)

Beginning in 1994, IGEN and Roche had been selling ECL instruments. (*See* D.I. 99 at 3)

At around the same time, Jacob Wohlstadter, the son of IGEN's CEO, was researching multi-array methodologies at another entity, MST. (*See id.* at 4) On November 30, 1995, IGEN and MST executed a joint venture agreement ("JVA"), which provided that "MST and IGEN have jointly prepared a Research Outline for a program of research and development (the 'Research Program') to be conducted by" Meso. (Ex. 8 at 1) The Recitals further provided that Meso was "organized for the purpose of conducting this research and development and, if successful, developing, manufacturing, marketing and selling products, processes and services." (*Id.*) Under the JVA, MST exclusively licensed its intellectual property to the joint venture while IGEN provided an exclusive license, significant financial investment, office and laboratory facilities, and research personnel. (*See* D.I. 109 at 2)

Also on November 30, 1995, IGEN and Meso executed a license agreement ("Meso License") governing IGEN's license grants to Meso. (Ex. 7) Section 2.1 of the Meso License states:

2.1. IGEN Technology. IGEN hereby grants to [Meso] an exclusive, worldwide, royalty-free license to practice the IGEN Technology to make, use and sell products or processes (A) developed in the course of the Research Program, or (B) utilizing or related to the Research Technologies; provided that IGEN shall not be required to grant [Meso] a license to any technology that is subject to exclusive licenses to third parties granted prior to the date hereof. In the event any such exclusive license terminates, or IGEN is otherwise no longer restricted by such license from licensing such technology to [Meso], such technology shall be, and hereby is, licensed to [Meso] pursuant hereto.

(*Id.* at 2)

“IGEN Technology” is defined in the Meso License as “all inventions, know-how, methods, procedures and other technology, whether or not patented or patentable, now or hereafter owned by, licensed to, or otherwise obtained by, IGEN” including “ECL Technology.” (*Id.* at 1-2) “Research Technologies” is defined in the JVA as “(i) selection and screening methods, . . . (ii) modified electrodes,³ . . . and (iii) multi-array diagnostic ‘Research Technologies’ specifically include, but are not limited to, . . . agents to extend the electrical potential of an electrode in the direction perpendicular to its surface” (Ex. 8 at 2)

The JVA provided that “[i]f no product has been developed by the time this Agreement is set to expire [in five years, Meso] shall prepare and submit to IGEN a written research plan and budget (the ‘Additional Research Budget’) for the conduct of additional research.” (*Id.* at 15) More than five years later, on February 15 and April 19, 2001, Meso sent IGEN Additional Research Budgets; the parties amended the JVA in August 2001. (Exs. 16, 19, 22) Under the “Additional funding if product developed” provision, the JVA defined a “developed product” as one that has been or is ready to be submitted for FDA approval or is declared developed by the Board of Managers. (Ex. 8 at 6)

In the meantime, in 1997, IGEN sued Roche for breach of the 1992 License. (*See* D.I. 99 at 5) A jury found that Roche materially breached the 1992 License; judgment for IGEN was affirmed on appeal on July 9, 2003. (*See id.* at 6) Thereafter, the 1992 License was terminated and, on July 24, 2003, IGEN and Roche executed a new license agreement (“2003 License”) to give Roche a non-exclusive license to IGEN’s ECL technology limited to human

³In a 2001 amendment to the JVA, “modified electrodes” was revised to “disposable electrodes.” (Ex. 22 at 2)

patient diagnostic uses. (See D.I. 99 at 6; D.I. 109 at 6; Ex. 34) Meso consented to the 2003 License to Roche. (See D.I. 109 at 6; Ex. T)

In 2003, BioVeris acquired IGEN's ECL technology and, in 2007, Roche acquired BioVeris. (See D.I. 99 at 6-7; D.I. 109 at 7)

In June 2010, Meso sued Roche in the Delaware Court of Chancery. (See D.I. 99 at 7) That Court's decision that Meso had consented to but was not a party to the 2003 License between IGEN and Roche, and that only BioVeris (as IGEN's successor-in-interest) could enforce the 2003 License against Roche for sales made outside the defined field in the 2003 License, was affirmed by the Delaware Supreme Court in June 2015. (See *id.*)

In February 2017, Roche filed the instant declaratory judgment action against Meso, to which Meso responded with counterclaims – including for breach of the Meso License – in April 2017. (D.I. 1, 10)

LEGAL STANDARDS

Under Rule 56(a) of the Federal Rules of Civil Procedure, “[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by “citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials,” or by “showing that the

materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). The “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;” a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial”). Thus, the “mere existence of a scintilla of evidence” in support of the nonmoving party’s position is insufficient to defeat a

motion for summary judgment; there must be “evidence on which the jury could reasonably find” for the nonmoving party. *Anderson*, 477 U.S. at 252.

DISCUSSION

The dispute between the parties is one of contract interpretation. “In a contract interpretation action, summary judgment is appropriate only where the contractual language is unambiguous – *i.e.*, subject to only one reasonable interpretation.” *Mylan Inc. v. SmithKline Beecham Corp.*, 723 F.3d 413, 418 (3d Cir. 2013) (internal quotation marks omitted). “If the nonmoving party presents a reasonable alternative reading of the contract, then a question of fact as to the meaning of the contract exists which can only be resolved at trial.” *Id.* (internal quotation marks omitted).

Under Delaware law,⁴ “[w]hen interpreting a contract, the role of a court is to effectuate the parties’ intent.” *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006). “Clear and unambiguous language should be given its ordinary and usual meaning.” *Id.* (internal quotation marks omitted). “A contract is not rendered ambiguous simply because the parties do not agree upon its proper construction. Rather, an ambiguity exists when the provisions in controversy are fairly susceptible of different interpretations or may have two or more different meanings.” *GMG Capital Invs., LLC v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 780 (Del. 2012) (internal quotation marks omitted). Courts do not ascribe “[a]n unreasonable interpretation [that] produces an absurd result or one that no reasonable person would have accepted when entering the contract.” *Osborn ex rel. Osborn v. Kemp*, 991 A.2d

⁴The parties agree that Delaware law governs. (See D.I. 109 at 2; D.I. 116 at 2)

1153, 1160 (Del. 2010). “Where a contract is ambiguous, the interpreting court must look beyond the language of the contract to ascertain the parties’ intentions.” *GMG Capital*, 36 A.3d at 780 (internal quotation marks omitted). If contract language is ambiguous, it may still be possible to grant summary judgment, if undisputed extrinsic evidence demonstrates the one and only correct meaning. *See GRT, Inc. v. Marathon GTF Tech., Ltd.*, 2012 WL 2356489, at *7 (Del. Ch. June 21, 2012).

Roche seeks summary judgment on seven separate issues relating to the scope of the Meso License under Section 2.1. Meso argues that Roche has failed to show that its interpretation of the contract is the only reasonable one, and/or that genuine disputes of material fact preclude summary judgment. As explained below, the Court agrees with Meso.

A. Scope of the “Research Program”

The Research Program aspect of the Meso License gives Meso “an exclusive . . . license to practice the IGEN Technology to make, use and sell products or processes (A) developed in the course of the Research Program.” (Ex. 7 at 2) Roche seeks summary judgment on four issues related to the scope of the Research Program.

1. Exclusive Rights to Patent Claims

The first issue concerns the scope of the exclusive rights that Section 2.1 gives to Meso. Meso argues that it has an exclusive right to practice IGEN’s patent *claims*, a right which was triggered by the development during the Research Program of products and processes that are covered by those claims. (*See* D.I. 109 at 13; Tr. at 48-49) Roche’s position, by contrast, is that Section 2.1 gives Meso “an exclusive license only to use ECL technology to make, use, or sell those *specific products and processes* that were advancements and improvements created in

the Research Program.” (D.I. 99 at 8) (emphasis added) Roche points out that Section 2.1 “says nothing about a grant of exclusive rights to any *patent claims*.” (D.I. 116 at 4; *see also* Tr. at 7-8)

Roche's interpretation would limit Meso's exclusive rights to the specific products and processes developed in the Research Program, while Meso's interpretation would more broadly extend Meso's exclusive rights to any product or process (whenever developed) that practices the claims of IGEN's patents.

Meso argues that Roche's narrow interpretation is illogical because it would require Meso to operate without a license until something was invented or first created in the Research Program. (*See* D.I. 109 at 12) (“If Roche were correct that [Meso] was only licensed to technology that it ‘invented or first created,’ then the joint venture would have been operating without a license to practice IGEN's ECL technology unless and until the joint venture ‘invented or first created’ something.”) According to Meso, the joint venture necessitated that Meso could use all of IGEN's patents to improve upon the prior art. (*See id.* at 10) Meso also criticizes Roche's interpretation on the basis that Meso would already have exclusive rights to whatever it invented or created in the Research Program through the joint venture, so Roche's interpretation of Section 2.1 of the Meso License would render it (at least close to) a nullity. (*See* Tr. at 50-51, 70-71; *see also* D.I. 109 at 13 (“If, as Roche argues, [Meso] was granted exclusive rights only to the exact products and processes it invented or newly created, then a third party could avoid infringing [Meso's] rights – and thereby defeat the purpose of the license being an exclusive one – simply by making minor adjustments to that specific embodiment.”))

Roche counters that Meso's interpretation is too broad, because it is illogical for Meso to

have an *exclusive* license to technology that pre-dated both the Research Program and the joint venture, particularly when products using the preexisting technology were already being commercially developed. (*See* D.I. 116 at 4-5; Tr. at 8-9)

The Court concludes that the parties have articulated more than one reasonable interpretation of the contract provision. Therefore, summary judgment on this issue will be denied.

2. Technology Pre-Dating the Research Program

Roche contends that ECL technology that pre-dated the Research Program could not have been, by definition, “developed in the course of the Research Program.” (Tr. at 8) Roche argues that “developed” in Section 2.1 is defined in Section 2.5.1 of the JVA, which defines a “developed product” as one that has been or is ready to be submitted for FDA approval or is declared developed by the Board of Managers. (*See id.* at 11; Ex. 8 at 6)

Meso responds that the word “developed” in Section 2.1 is not to be given the definition of Section 2.5.1 of the JVA, because the term defined there is actually “developed product,” and it is used only in the context of funding, as reflected in the fact that it was deleted by the parties. Also, the word “developed” appears in other spots in the parties’ agreements. (*See* Tr. at 51, 69) Roche concedes these points. (*See id.* at 61, 63)

The Court agrees with Meso that the word “developed” in Section 2.1 must be given its ordinary and usual meaning, not the meaning supplied in Section 2.5.1 of the JVA, for the reasons stated by Meso. In the Court’s view, then, the parties agreed in the Meso License that “one can ‘develop’ something that already exists,” for instance by improving or otherwise changing it. (D.I. 109 at 9) (citing dictionary definitions)

Roche argues that even if “developed” were given its ordinary meaning, that suggests only that Meso may have exclusive rights to improvements over preexisting technology, but *not* to the preexisting technology itself. (*See* Tr. at 8-11) Meso responds that the Meso License was executed in a “unique business context,” in which IGEN “shift[ed its] rights from itself to a joint venture in which it is a participant and over which it has significant control.” (*Id.* at 29) In that context, Meso argues that the intent of the joint venture was to further develop upon the IGEN Technology that already existed, making it reasonable to license to the joint venture already-existing technology as well as improvements. (*See* D.I. 109 at 9-10)

The Court concludes that the parties have articulated more than one reasonable interpretation. Therefore, summary judgment on this issue will be denied.

3. “Developed” Products in the Research Program

Roche also seeks summary judgment that under Section 2.1, Meso did not develop any products in the course of the Research Program by April 2001, the point at which Meso sent two Additional Research Budgets to the joint venture oversight committee. (*See* D.I. 99 at 5, 12-13) Roche points to deposition testimony of Wohlstedter as purportedly supporting its position. (*See* Tr. at 12 (citing Ex. 21 at 341); *see also* D.I. 109 at 11 (citing same)) Meso argues that according “developed” its usual and ordinary meaning in Section 2.1, as the Court has decided is appropriate (see above), there is evidence that Meso did develop products during the Research Program. (*See* D.I. 109 at 4-5) For example, IGEN had indicated in the 2001 amendment to the Meso License that IGEN had reviewed research summaries regarding developments from the Research Program. (*See id.* at 5; Tr. at 53)

As the record reflects genuine disputes of material fact as to whether any products or

processes were developed during the course of the Research Program, the Court will deny summary judgment on this issue.

4. Development of Sulfo-TAG

Roche seeks summary judgment that Sulfo-TAG, which is covered by IGEN's '939 patent, was not developed in the course of the Research Program. (*See* Tr. at 13-14, 49) The parties point to conflicting evidence as to whether Sulfo-TAG was developed during the course of the Research Program. (*See* D.I. 99 at 13-14; D.I. 109 at 15) The Court agrees with Meso that ownership of the patent is irrelevant to their dispute. Still, the overall record demonstrates a genuine dispute of material fact. Accordingly, the Court will deny summary judgment on this issue.

B. Scope of “Research Technologies”

The Meso License also gave Meso an exclusive “license to practice the IGEN Technology to make, use and sell products or processes . . . (B) utilizing or related to the Research Technologies.” (Ex. 7 at 2) Roche seeks summary judgment on two issues related to the scope of the Research Technologies license: whether it encompasses (1) flow cells using platinum electrodes and (2) tripropylamine (“TPA”), a coreactant used in the ECL reaction.

1. “Disposable Electrodes”

It is undisputed that “Research Technologies” include “disposable electrodes.” (*See* D.I. 99 at 14; D.I. 109 at 16) The dispute is whether “disposable electrodes” includes platinum reusable electrodes such as those used by IGEN and Roche. (*See* Tr. at 15) Meso contends it does; Roche contends it does not. Roche argues that the term “disposable electrode” unambiguously does not include platinum reusable electrodes and cites technical evidence in

support. (*See id.* at 15-18; D.I. 99 at 15-16) Meso argues that this dispute presents a factual question that cannot be resolved until after discovery, as part of Track 2 of this litigation. (*See* Tr. at 33-36)

The Court agrees with Meso that, because the factual record concerning Roche's products and use of disposable electrodes is still being developed, the Court should (and will) deny summary judgment on this issue.

2. TPA

With respect to TPA, the first issue is whether the definition of "Research Technologies" in the JVA includes the second sentence, which begins "'Research Technologies' specifically include, but are not limited to" (Ex. 8 at 2) The ordinary meaning of the language in the second sentence of the definition of "Research Technologies" unambiguously defines the term to include the list of items in that sentence. Thus, an "agent[] to extend the electric potential of an electrode in the direction perpendicular to its surface" is one of many "Research Technologies."

The parties next dispute whether TPA is such an agent. At present, the Court does not have sufficient technical assistance or understanding to make this determination. Meso argues that Roche provides no support for its statement that TPA does not extend the electric potential. (*See* Tr. at 36) Roche counters that even if TPA does extend the electric potential, it was not known to be able to do so when the Meso License was negotiated in 1995. (*See* D.I. 99 at 17; Tr. at 20) Meso takes the view that contemporaneous knowledge is irrelevant because the Meso License unambiguously covers agents having this (even unappreciated) ability. (*See* Tr. at 38)

Roche contends that Meso's position is illogical: since TPA had "served as the coreactant of choice for ECL instruments," including IGEN's instrument, IGEN would not have given Meso

“exclusive rights to the coreactant needed for all of IGEN's instruments and assays and yet never disclosed that fact” to the SEC, as IGEN was a publicly-traded company. (*See* D.I. 99 at 17) Meso responds that by 1995, IGEN was principally a licensing company and (through the joint venture) controlled Meso, so Meso would not have been able to sue IGEN for infringement of Meso's exclusive rights to TPA (at least not without IGEN's – unlikely – consent). (*See* Tr. at 42-45) Even though the joint venture ended in February 2004 and Meso did not assert its exclusive rights to TPA until 2007, Meso argues that there was no reason to have done so – by 2004, Roche was the only entity using TPA and Meso had already consented to Roche's rights in the human diagnostics field. (*See id.* at 46-47, 65-66) Roche notes that IGEN did not control Meso after the joint venture ended, so the risk Roche identifies to itself from Meso was very real from that point on. (*See id.* at 65) Meso responds that it did not face a threat until 2007, when Roche and Bioveris joined forces and still required TPA. (*See id.* at 69)

Roche also points to the undisputed facts that, if Meso is correct, “Meso held exclusive rights to the crown jewels of the IGEN technology,” but failed to “list those rights as an asset when the Meso joint venture was valued.” (D.I. 116 at 1)

The record demonstrates genuine disputes of material fact, including whether TPA is an agent that extends the electric potential of an electrode in the direction perpendicular to its surface and, if so, whether the Meso License was intended to cover TPA. Accordingly, the Court will deny summary judgment on this issue.

C. Meso's Springing Rights

The final dispute concerns the scope of the springing rights Meso was granted upon the 2003 termination of Roche's 1992 License. Section 2.1 of the Meso License provides that

Meso will not be granted “a license to any technology that is subject to exclusive licenses to third parties granted prior to” the Meso License, but if such a third party license terminates, “such technology shall be, and hereby is, licensed to [Meso] pursuant hereto.” (Ex. 7 at 2) Meso’s position is that upon termination of the 1992 License, Meso acquired all of Roche’s license rights under that agreement, regardless of whether those rights involve IGEN Technology “(A) developed in the course of the Research Program, or (B) utilizing or related to the Research Technologies” (*See, e.g.*, D.I. 109 at 20) (discussing § 2.1 of Meso License) Roche’s position is that termination of the 1992 License “did not extend the scope of Meso’s rights beyond the technology specified in Section 2.1 of the Meso License.” (D.I. 99 at 20) In other words, Roche argues that upon termination of the 1992 License, “Meso’s license only would expand to include the specific technology license rights that Meso otherwise would have received in 1995 but for the pre-existing licenses.” (D.I. 116 at 14-15)

Meso’s response largely consists of pointing to an email message sent by an attorney for Roche to an attorney for IGEN in August 2002 (before the 1992 License was terminated). (*See* Tr. at 57; *see also* D.I. 109 at 20 (citing Ex. FF) The Roche attorney, Ralf-Reinhard Boer, wrote: “Meso[’s] . . . exclusive rights in the ECL Technology appeared to encompass all of Roche’s rights under the 1992 License Agreement once that Agreement was terminated or became non-exclusive.” A reasonable factfinder, taking the evidence in the light most favorable to Meso, could find from this that Meso’s interpretation of its springing rights is correct: namely, that “upon termination of an exclusive license from IGEN to a third party regarding the IGEN technology, [Meso] would step into the shoes of the third-party licensee.” (D.I. 109 at 20)

The Court concludes that the parties have articulated more than one reasonable

interpretation. Therefore, summary judgment on this issue will be denied

CONCLUSION

For the reasons stated, Roche's Motion for Summary Judgment (D.I. 98) will be denied.

An appropriate Order follows.